

REMARKS

Entry of the foregoing, reexamination, and reconsideration of the above-identified application, pursuant to and consistent with 37 C.F.R. § 1.111, are respectfully requested.

Status

As is correctly reflected in the Office Action Summary, Claims 39-42 were pending in this application. Claims 39-42 stand rejected.

Summary of Claim Amendments

By the foregoing claim amendments, Applicants have amended independent Claim 39 to specify that "said epitope is present in GAD₆₅ but not GAD₆₇." Further by the foregoing amendments, Applicants have added new Claims 43 and 44 which specify, respectively, the nucleic acid of Claim 39 "wherein said nucleic acid encodes an epitope which binds serum from an IDDM patient" and "wherein said nucleic acid encodes the amino terminal 100 amino acids of GAD₆₅." Support for these amendments may be found throughout the Specification, and at least at Page 9, Lines 20-28 and at Page 33, Line 6 through Page 35, Line 23. Accordingly, no new matter has been added.

Finally by the foregoing claim amendments, Applicants have amended Claim 42 to specify that the host cell is isolated. Support for this amendment may be found throughout the Specification, and at least at Page 8, Lines 5-9. Accordingly no new matter has been added.

Information Disclosure Statement

Applicants hereby furnish thirty-eight (38) (non-patent) publications listed on the form PTO-1449 corresponding to the Information Disclosure Statement filed November 24, 2003, which the Examiner indicated were not available.¹ Should the Examiner need any additional publications, she is invited to contact Applicants' undersigned representative so that those publications will be considered. Applicants respectfully request that an Examiner-initialed copy of the form PTO-41449 be returned to Applicants.

Rejection Under 35 U.S.C. § 112, First Paragraph – Enablement

Claims 39-42 were rejected under 35 U.S.C. § 112, First Paragraph, as purportedly not enabled. This rejection is respectfully traversed.

As set forth in Applicants' Amendment and Reply filed July 24, 2006, enablement is not precluded by the necessity of some experimentation. The only requirement is that such experimentation must not be undue. *See, e.g., In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988). Applicants respectfully reiterate that *undue* experimentation is not necessary to make or use the claimed invention.

Applicants' Amendment and Reply filed July 24, 2006 set forth why one of skill in the art as of the application's August 15, 2003, filing date would have readily been able to determine features that define GAD₆₅ epitopes. In turn, one of skill in the art would have been readily able to make and use the claimed invention.

Not to acquiesce in the Examiner's continued rejection, but solely to facilitate prosecution, Applicants have amended independent Claim 39 to specify that "said epitope is

¹ Applicants have determined that the fifteenth non-patent literature document on the November 24, 2003, form PTO-1449 was listed in error. The correct citation is listed as the nineteenth non-patent literature document "Wyborski, et al. ..." Accordingly, the fifteenth-listed non-patent literature document is not provided with this submission.

present in GAD₆₅ but not GAD₆₇.” Applicants believe this amendment addresses the Examiner’s concern that Claim 39 previously “read on an unlimited amount of epitopes and a protein fragment contained in the GAD₆₅ structure and [that] no guidance is provided nor a direct correlation between structure and function made.” *Office Action mailed October 23, 2006, Page 6*. Moreover, newly-added Claims 43 and 44 specify, respectively, the nucleic acid of Claim 39 “wherein said nucleic acid encodes an epitope which binds serum from an IDDM patient” and “wherein said nucleic acid encodes the amino terminal 100 amino acids of GAD₆₅.” Applicants believe these claims provide even further specificity for the epitopes, as well as the guidance and correlation the Examiner seeks.

In view of the foregoing claim amendments, Applicants respectfully request withdrawal of the rejection of Claims 39-42 under 35 U.S.C. § 112, First Paragraph, for lack of enablement.

CONCLUSION

It is respectfully submitted that all rejections have been overcome by the above amendments. Thus, a Notice of Allowance is respectfully requested.

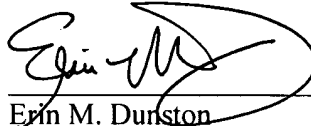
In the event that there are any questions relating to this Amendment or to the application in general, it would be appreciated if the Examiner would contact the undersigned attorney by telephone at (202) 373-6162 so that prosecution of the application may be expedited.

The Director is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-2518.

Respectfully submitted,
BINGHAM MCCUTCHEN, LLP

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By:



Erin M. Dunston
Registration No. 51,147

Bingham McCutchen LLP
Three Embarcadero Center
San Francisco, California 94111-4067
Local Telephone: (202) 373-6000
Local Facsimile: (202) 373-6001